

# Development of the Italian version of the Pain Stages of Change Questionnaire in patients with chronic low back pain: cross-cultural adaptation, confirmatory factor analysis, reliability and validity

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## Introduction

Low back pain (LBP) is one of the leading causes of disability and reduction of quality of life in adults. It has a prevalence of about 23%, with 11–12% of the population being disabled because of chronic symptoms. It is associated with psychosocial and occupational limitations and accounts for about 90% of medical and related expenses (Balagué *et al.*, 2012). Given the biopsychosocial nature of LBP, multidisciplinary programmes have been recommended to improve physical and psychosocial functioning, adaptive coping responses, activity pacing and gradual exposure to exercise (Van Middelkoop *et al.*, 2011). However, patients with chronic LBP may differ in their readiness to adopt self-management approaches, expected to facilitate their willingness to participate in multidisciplinary programmes (Glenn and Burns, 2003; Newman *et al.*, 2004).

To investigate patient engagement in behavioural change, Kerns *et al.* (1997) proposed a model for conceptualizing the process of adopting a self-management approach to chronic pain, the Pain Stages of Change Questionnaire (PSOCQ). On the basis of the Pain Readiness to Change Model (Jensen *et al.*, 2003), derived from the Transtheoretical Model of Behaviour Change (Prochaska and DiClemente, 1982), the PSOCQ assesses different levels of readiness to change and characterizes individuals with respect to their approach to their pain concern: precontemplation (i.e. belief that management of pain is the responsibility of medical professionals), contemplation (i.e. consideration of adopting a self-management approach but reluctance to give up pursuit of a medical solution), action (i.e. beginning attempts to improve self-management skills) and maintenance

(i.e. commitment to pain self-management) (Kerns *et al.*, 1997).

The PSOCQ has been shown to support a four-factor structure, to be internally consistent and reliable, and to have satisfying criterion-related and discriminant validity (Kerns *et al.*, 1997; Kerns and Habib, 2004). The PSOCQ showed the ability to predict completion of outpatient and inpatient self-management programmes (Biller *et al.*, 2000; Kerns and Rosenberg, 2000), and improvements in pain coping during treatment (Jensen *et al.*, 2003).

Dutch and Norwegian translations of the PSOCQ have already been validated, shown to be reliable and allowed comparisons between different countries and cultures (Dijkstra *et al.*, 2001; Strand *et al.*, 2007).

As an Italian version of the PSOCQ has not been developed with full cross-cultural adaptation and psychometrically analysed, Italian researchers and clinicians are limited in sharing validated outcomes. The aim of this study was to describe the adaptation and validation of the Italian version of the PSOCQ in patients with chronic LBP.

## Methods

This study was approved by the Institutional Review Board of the Salvatore Maugeri Foundation's Scientific Institute in Lissone (Italy).

### Patients

Outpatients attending the Physical Medicine and Rehabilitation Unit of the Salvatore Maugeri Foundation's Scientific Institute in Lissone (Italy) and three affiliated centres were recruited between September 2011 and December 2012. Inclusion criteria were chronic, non-specific LBP (lasting more than 12 weeks), age greater than 18 years and the ability to read and speak Italian fluently. Exclusion criteria were acute (lasting up to 4 weeks) and subacute LBP (lasting up to 12 weeks), central or peripheral neurological signs, systemic illness and psychiatric and mental deficits. Patients with recent cerebrovascular accidents, myocardial infarctions or chronic lung or renal diseases were excluded.

The patients' demographic and clinical characteristics were recorded by a research assistant. All of the eligible patients provided their written consent to participate.

### Sample size calculation

It was based on the rule of 10 patients per item (Terwee *et al.*, 2007).

### Translation and cross-cultural adaptation

This was done in accordance with the protocol issued by the American Association of Orthopaedic Surgeon Outcomes Committee (Beaton *et al.*, 2000).

### Step 1: translation into Italian

The items taken from the original PSOCQ were translated into Italian with the aim of retaining the concepts of the original while using culturally and clinically fitting expressions. Two translations were made independently by two Italian translators, one of whom was unfamiliar with the measure. Keeping the language colloquial and compatible with a reading age of 14 years, the poorer wording was improved by means of discussion between the translators. Step 1 ended when a common adaptation was agreed. None of the items were excluded.

### Step 2: back-translation into English

Two independent bilingual translators whose mother tongue was English back-translated the initial translation; they were selected because they did not have a medical background and were unaware of the concepts being explored. The aim was to ensure that the Italian version reflected the same item content as the original version and was conceptually equivalent.

### Step 3: expert committee

The translations were submitted to a bilingual committee of clinicians, methodologists and the translators. To identify any difficulties or mistakes, the committee explored the semantic, idiomatic and conceptual equivalence of the items and answers. Step 3 ended when a prefinal version was agreed.

### Step 4: test of the prefinal version

The scale was administered to 50 patients with chronic LBP with the aim of probing what was meant by each item and the chosen response. These findings were re-evaluated by the experts, although no further adjustment was required.

### Scale properties and data analyses

All of the methodological criteria for the investigation of psychometric properties suggested by Terwee *et al.* (2007) were followed, except for 'responsiveness,' because this was a cross-sectional study.

### Acceptability

The time needed to answer the questionnaire was recorded. Once completed, the patients were asked about any problems they encountered; the examiners checked the data, including any missing or multiple responses.

### Factor analysis

Confirmatory factor analysis was used, with each item being specified to load on its subscale as hypothesized originally (Kerns *et al.*, 1997). Model fit was assessed using  $\chi^2$  statistics, the comparative fit index, the normed fit index, root-mean square error of approximation (RMSEA) and the 90% confidence intervals of

RMSEA (Bollen and Long, 1993). A ratio between the  $\chi^2$  and *df.* lower than 3, comparative fit index and normed fit index values of at least 0.90, and RMSEA values of up to 0.08 indicated a good fit (Hu and Bentler, 1999).

### **Reliability**

This was investigated by internal consistency and test-retest reliability. The first reflects the inter-relatedness among items, which is considered good if the value of Cronbach's  $\alpha$  is greater than 0.70; the second measures reliability over time by administering the same questionnaire to the same patients after a certain interval (in our case, 7 days to avoid the natural fluctuations in symptoms associated with possible memory effects). The intraclass correlation coefficient (2,1), was used to test the agreement of the results in all of the patients, with good and excellent reliability being, respectively, indicated by values of 0.60–0.80 and greater than 0.80 (Terwee *et al.*, 2007).

### **Distribution and floor/ceiling effects**

Descriptive statistics were calculated to determine distribution and floor/ceiling effects, which were considered to be present when more than 15% of the patients received either the lowest or highest possible scores (Terwee *et al.*, 2007).

### **Content validity**

It was based on patients' answers to specific questions. It investigated the aim of the measurement (Question: 'Do you think pain readiness to change constitutes the aim of this questionnaire?'; Answer options: Yes/No), the target population (Question: 'Do you think the items described here may be related to chronic LBP?'; Answer options: Yes/No) and the concepts being measured, with special attention to the relevance (Question: 'Do you think these items are relevant to evaluate pain readiness to change?'; Answer options: Yes/No) and completeness (Question: 'Do you think that the items presented comprehensively reflect pain readiness to change?'; Answer options: Yes/No) of the questionnaire. The hypotheses were considered acceptable if the percentage rate of affirmative answers was greater than 90% (Terwee *et al.*, 2007).

### **Construct validity**

This was investigated by means of hypothesis testing the outcome measures (Terwee *et al.*, 2007). It was hypothesized *a priori* that the correlation (i.e. the extent to which an instrument's score relates to the score of the theoretical construct of another instrument as expected) between PSOCQ-I Precontemplation with measures of catastrophizing, kinesiophobia, disability and pain intensity would be moderate; the correlation between PSOCQ-I Contemplation, Action and Maintenance with the same measures would be low; and the correlation between the PSOCQ-I scales with measures of

anxiety/depression would be moderate to low. Pearson's correlations of  $r < 0.30$  = little correlation;  $0.30 \leq r \leq 0.60$  = moderate correlation; and  $r > 0.60$  = high correlation (Atkinson and Nevill, 1997).

Sensitivity to change was estimated by means of the minimum detectable change (MDC) calculated by multiplying the standard error of the measurements (SEM) by the *z*-score associated with the desired level of confidence (95% in our case) and the square root of 2, which reflects the additional uncertainty introduced by using difference scores on the basis of measurements made at two time points (in our case on days 1 and 7). The SEM was estimated using the formula  $SEM = SD[(1-R)1/2]$ , where SD is the baseline SD of the measurements and *R* is the test-retest reliability coefficient (Terwee *et al.*, 2007).

## **Outcome measures**

### **Pain Stages of Change Questionnaire**

This is a self-administered 30-item measure of individuals' readiness to adopt a self-management approach to their chronic pain conditions. It is composed of four scales: Precontemplation (seven items), Contemplation (10 items), Action (six items), and Maintenance (seven items). Each item is coded on a five-point scale, from strongly disagree (1) to strongly agree (5); raw scores are transformed into a mean score for each scale, with higher scores indicating stronger endorsement of items representing each readiness stage domain.

### **Pain Catastrophising Scale**

This 13-item self-report questionnaire assesses catastrophizing. Each item is scored using a five-point scale ranging from 0 (never) to 4 (always). The total score is calculated by adding the scores of the individual items (range 0–52), with higher scores representing greater catastrophizing (Sullivan *et al.*, 1995). We used the Italian version, which proved to be reliable and valid (Monticone *et al.*, 2012).

### **Tampa Scale of Kinesiophobia**

This self-report questionnaire assesses fear-avoidance behaviours (Kori *et al.*, 1990). We used the Italian 13-item version with the reversed items removed, which proved to be reliable and valid (Monticone *et al.*, 2010). Each item is scored using a four-point Likert scale ranging from 1 (strongly disagree) to 4 (strongly agree), and the total score is calculated by adding the scores of the individual items (range 13–52), with higher scores representing greater kinesiophobia.

### **Roland and Morris Disability Questionnaire**

This 24-item self-report questionnaire allows a comprehensive evaluation of back problems (Roland and Morris, 1983). Each item is scored 1 if declared applicable to the respondent and 0 if not, and the total score varies from

0 (no disability) to 24 (maximum disability). We used the Italian version, which proved to be reliable and valid (Padua *et al.*, 2002).

### Numerical Rating Scale

This is an 11-point rating scale ranging from 0 (no pain at all) to 10 (the worst imaginable pain) (Huskisson, 1974).

### Hospital Anxiety and Depression Scale

This assesses anxiety and depression disorders (Zigmond and Snaith, 1983), and consists of 14 items that create subscale scores for anxiety (HADS-A, seven items) and depression (HADS-D, seven items). The total score for each subscale is calculated by adding the scores of the individual items (0–3), ranging from 0 (good) to 21 (poor). We used the Italian version, which proved to be reliable and valid (Costantini *et al.*, 1999).

### Statistical analyses

The analyses were carried out using the Italian SPSS 20.0 software (SPSS Italia, Bologna, Italy); confirmatory factor analysis was performed using SPSS Amos (SPSS Italia).

## Results

### Participants

Except for the participants enrolled during the test of the prefinal version, a total of 332 patients were invited to participate and, of these, 308 fulfilled the inclusion criteria; these were 163 women (52.9%) and 145 men (47.1%), mean age  $48.70 \pm 12.61$  years (range 20–71). The median duration of LBP was 12 months (range 3–120). The mean BMI was  $24.63 \pm 3.50$ . Table 1 shows their general characteristics.

### Translation and cross-cultural adaptation

The questionnaire was translated into Italian using a process of forward–backward translation involving four translators; it took 2 months to obtain a culturally adapted version. Special attention was focused on translating the verbs ‘to deal with’ and ‘to cope’ (in Italian the verb used was always ‘affrontare’), and ‘to manage’ (in Italian the verb chosen was ‘gestire’). Also, attention was focused on translating the words ‘plan’ (in Italian the term chosen was ‘piano’), ‘ways’ (in Italian the term used was ‘modi’) and ‘strategies’ (in Italian the term chosen was ‘strategie’). We also decided not to translate ‘medical cure’ as ‘drug’ because other therapeutic options such as physical modalities, physiotherapy or physical exercises could also be considered among medical cures (in Italian, the term chosen was ‘cure mediche’). Finally, the four subscales were kept separate to improve the clarity of the questionnaire layout. A further review by experts and the testing of the prefinal version confirmed the correctness of the process of translation/back-translation and the content of the items. The PSOCQ-I is available upon request from the corresponding author.

## Scale properties

### Acceptability

All of the questions were well accepted. The questionnaire was completed in  $5.90 \pm 7.75$  min. There were no missing responses or multiple answers.

### Factor analysis

The RMSEA value obtained did not initially fulfil the criteria for a good fit, and so the model was adjusted on the basis of modification indices: in Precontemplation, Contemplation and Maintenance, we added covariance between error terms for the item pairs (as shown in Table 2); in Action, item no. 19 was removed from the model. Precontemplation, Contemplation and Action showed acceptable criteria, whereas Maintenance was

**Table 1** General characteristics of the population ( $n=308$ )

Variables	N (%)
Marital status	
Unmarried	145 (47.1)
Married	163 (52.9)
Employment	
Employee	156 (50.7)
Self-employed	54 (17.5)
Housewife	34 (11.0)
Pensioner	64 (20.8)
Education	
Elementary school	30 (9.8)
Middle school	74 (24.0)
Upper school	115 (37.3)
University	89 (28.9)
Smoking	
Yes	72 (23.4)
No	236 (76.6)
Use of drugs	
Antidepressants	27 (8.8)
Analgesics	102 (33.1)
Muscle relaxants	37 (12.0)
NSAIDs	63 (20.4)
None	79 (25.7)
Comorbidities (principal)	
Hypertension	74 (24.1)
Non-insulin-dependent diabetes mellitus	21 (6.8)
Heart disease	19 (6.2)
Gastroenteric disease	25 (8.1)
Liver disease	18 (5.8)
None	151 (49.0)

**Table 2** Results of confirmatory factor analysis testing of factorial validity

Model	$\chi^2/d.f.$	CFI	NFI	RMSEA	90% CI
Precontemplation <sup>a</sup>	2.20	0.99	0.98	0.06	0.03–0.09
Contemplation <sup>b</sup>	3.57	0.95	0.94	0.08	0.07–0.10
Action	2.90	0.99	0.99	0.08	0.04–0.13
Maintenance <sup>c</sup>	4.32	0.98	0.97	0.10	0.07–0.13

CFI, comparative fit index; CI, confidence interval; NFI, normed fit index; RMSEA, root-mean square error of approximation.

<sup>a</sup>The model included specified covariance between error terms for items 1–2 and 4–6.

<sup>b</sup>The model included specified covariance between error terms for items 10–15, 11–12, 13–14 and 16–17.

<sup>c</sup>The model included specified covariance between error terms for items 24–27, 24–28 and 25–28.

**Table 3 Floor/ceiling effects and reliability of the Pain Stages of Change Questionnaire**

Subscales	Mean (SD)	Floor/ceiling effects (%)	Internal consistency ( $\alpha$ )	Test-retest (ICC and 95% CI)
Precontemplation (7 items)	2.64 (0.96)	0/0	0.93	0.81 (0.77–0.84)
Contemplation (10 items)	3.43 (0.75)	0/0	0.91	0.74 (0.69–0.79)
Action (5 items)	3.76 (0.95)	0/0	0.93	0.77 (0.72–0.81)
Maintenance (7 items)	3.77 (0.86)	0/0	0.92	0.77 (0.73–0.82)

CI, confidence interval; ICC, intraclass coefficient correlation.

less coherent in this dataset because only two out of four fitting criteria were fulfilled. The item-scale correlations were 0.73–0.88 for Precontemplation, 0.63–0.88 for Contemplation, 0.81–0.95 for Action and 0.67–0.89 for Maintenance.

The subsequent analyses were carried out considering a four-factor 29-item solution.

### **Floor/ceiling effects**

No significant floor/ceiling effects were found (Table 3).

### **Reliability**

Cronbach's  $\alpha$  was satisfactory (0.91–0.93). Test-retest reliability was good (intraclass correlation coefficients: 0.74–0.81). Table 3 shows the full results.

### **Content validity**

The percentage rate of patients' affirmative answers was always greater than 90%. The content of the items was considered adequate, appropriate for the target population, comprehensive and relevant for investigating pain readiness to change in this population.

### **Construct validity**

All of the *a priori* hypotheses were achieved. Table 4 summarizes the correlations.

### **Sensitivity to change**

The MDC of the Precontemplation, Contemplation, Action and Maintenance was, respectively, 1.16, 1.06, 1.27 and 1.14.

## **Discussion**

This paper describes the adaptation and validation of the PSOCQ in Italian patients with chronic LBP. Analysis of the psychometric properties of an outcome measure is a continuous process recommended to strengthen its properties and expand its applicability in specific contexts and countries (De Vet *et al.*, 2011).

The results of the adaptation process indicate that it was developed successfully following international guidelines. The experts played an important role during the re-evaluation of the process and confirmed the quality of the work carried out. The on-field text confirmed the comprehensibility of the items, leading to a valid measure of another culture's conception of health that allows data comparability and cross-national studies.

The questionnaire was acceptable to our population and required about 5 min to be completed; it responded satisfactory in terms of the requirements of relevance and completeness, and seemed to be fully applicable in everyday clinical practice. No significant floor/ceiling effects were found, which suggests that the subscales assess their constructs correctly.

Except for item no. 19, which was removed from the adapted questionnaire, our findings confirmed the originally proposed structure of the PSOCQ, suggesting that pain readiness to change can be described as a process with four behavioural components (Kerns *et al.*, 1997; Kerns and Habib, 2004). An exploratory factor analysis carried out in Australian participants showed two factors, the first labelled 'Contemplation', on which Contemplation loaded, and the second named 'Engagement', on which the remaining subscales loaded (Strong *et al.*, 2002). Exploratory factor analyses were also carried out in Dutch, Norwegian and UK populations, providing support to a three-factor solution, with Action and Maintenance loading on the same factor (Dijkstra *et al.*, 2001; Carr *et al.*, 2006; Strand *et al.*, 2007). Moreover, as our results indicated that Maintenance had the worst fitting performance to the model, further investigations are recommended to explore the validity of this subscale and, as found previously, its correlations with Action (Dijkstra *et al.*, 2001; Carr *et al.*, 2006; Strand *et al.*, 2007).

Our sample showed that the PSOCQ-I subscales were internally consistent, with higher estimates than original findings (0.77–0.86) (Kerns *et al.*, 1997). They were also higher than Australian (0.64–0.84), Dutch (0.61–0.86) and Norwegian (0.68–0.87) values (Dijkstra *et al.*, 2001; Strand *et al.*, 2007).

Test-retest reliability was satisfactory and our findings were higher than the original findings (0.74–0.88) (Kerns *et al.*, 1997). Reliability over time was not investigated in other samples and comparisons are not possible.

As expected, catastrophizing, fear of movement, reduced function and pain intensity correlated more with Precontemplation behaviours than with the other PSOCQ-I subscales. In line with other studies (Jensen *et al.*, 2004; Burns *et al.*, 2005; Carr *et al.*, 2006), our findings advocate that, to achieve better outcomes, PSOCQ-I subscales could be useful for directing interventions with patients in their Precontemplation stage requiring more intensive preparation before

**Table 4 Construct validity**

Outcome measures	Precontemplation	Contemplation	Action	Maintenance
PCS	0.318**	0.039**	-0.016**	-0.062**
TSK	0.385**	0.024	-0.098**	-0.164**
RMDQ	0.320**	-0.004**	-0.061	-0.073**
NRS	0.335**	-0.020**	-0.088**	-0.170
HADS-anxiety	0.150**	0.040	-0.061	-0.132*
HADS-depression	-0.113*	0.024	0.186**	0.145*

Pearson's correlations between the PSOCQ-I subscales and the PCS, TSK, RMDQ, NRS, HADS-Anxiety and HADS-Depression.

HADS, Hospital Anxiety and Depression Scale; NRS, Numerical Rating Scale; PCS, Pain Catastrophising Scale; RMDQ, Roland Morris Disability Scale; TSK, Tampa Scale of Kinesiophobia.

\* $P < 0.05$ .

\*\* $P < 0.01$ .

cognitive-behavioural treatments as well as patients in their Contemplation, Action and Maintenance stages being more responsive to treatments promoting self-management strategies. Poor correlations were found between PSOCQ-I subscales and anxiety/depression, suggesting that in our sample readiness to change was not related to mood disorders as found previously (Jensen *et al.*, 2003); this might depend on the estimates of the domain investigated, the timing of assessment and the familiarity to interpret items correctly.

PSOCQ-I proved to be sensitive to change in this sample. Given the degree of repeatability, the SEM and MDC were reduced and ensured that it could identify changes in the scores exceeding the threshold of instrument noise. At a 95% confidence level, the MDC indicated that, if a participant shows a change after a given intervention of more than 1.16, 1.06, 1.27 and 1.14 points in Precontemplation, Contemplation, Action and Maintenance, respectively, it would not be a measurement error.

Our study has some limitations. First, its cross-sectional design means that significant correlations should not be confused with causal effects. Second, the relationships between pain readiness to change and physical tests were not considered because only questionnaires were used. Third, our study was restricted to chronic LBP and it is uncertain whether its findings can be extended to other spinal complaints, particularly chronic neck pain.

## Conclusion

The PSOCQ-I administered in patients with chronic LBP confirms the originally proposed four-factor structure, and is reliable, valid and sensitive to change. It can be recommended for clinical and research purposes.

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The study was approved by the Salvatore Maugeri Foundation's Scientific Institute in Lissone (Italy) Institutional Review Board and was carried out in accordance with ethical and humane principles of research.

## Conflicts of interest

There are no conflicts of interest.

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